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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 9 1993

**MEMORANDUM**

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Asulam (Acid): Product Chemistry Data Requirements. CBRS # 10955. DP Barcode: D185101.

FROM: Leung Cheng, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

THROUGH: Francis B. Suhre, Section Head
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

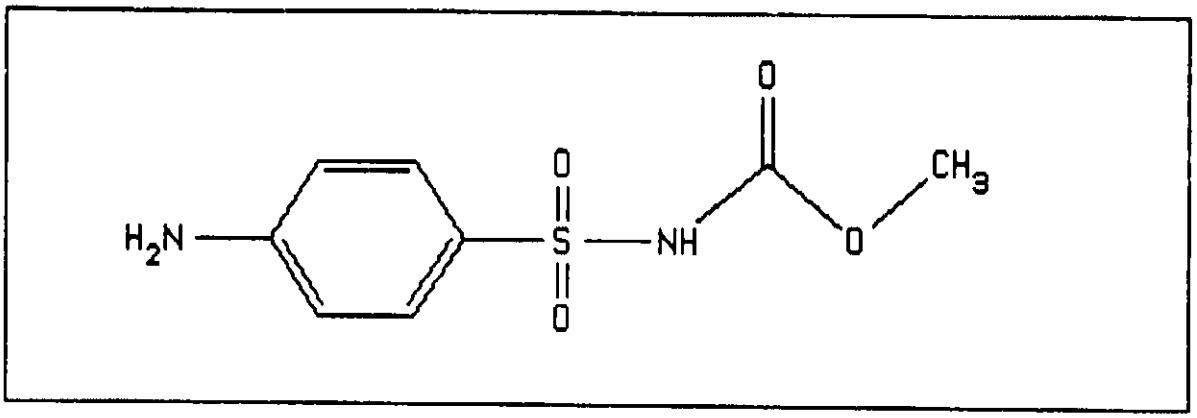
TO: Mario Fiol/Linda Propst, PM # 73
Reregistration Branch
Special Review/Reregistration Division (H7508W)

Rhone-Poulenc has submitted a response via their letter of 10/20/92 to our review of product chemistry data requirements of sodium salt of asulam (F. Toghrol, 8/27/92, CBRS # 10086). CBRS's instruction is to reexamine the product chemistry data requirements with respect to the information provided in the 10/20/92 letter. The chemical structure of asulam, methyl sulfanilylcarbamate, is shown on page two.

The 8/27/92 CBRS review noted "some discrepancies between the Asulam Product Chemistry Chapter (8/28/87) and the Asulam Product and Residue Chemistry Reregistration Standard Update dated 1/15/91 regarding asulam (acid) 86.4% T (EPA Reg. No. 264-451; PC Code No. 106901) and that of asulam-sodium salt T (PC Code No. 106902)...All data requirements must be reassessed once a response is received to the subject memo...because there are questions about what has served as test substance in the past, what chemical (acid or sodium salt) serves as ai, and whether one or both ai's are contained within MPs and EPs."

The registrant responded that:

a) data for asulam sodium is being submitted to support registration of MP and EP containing asulam and its sodium salt as active ingredients, where applicable;



b) EPA Reg # 264-447, an EP, contains the sodium salt of asulam as the active;
c) asulam was not isolated in their production process but was an integrated product used to manufacture the sodium salt of asulam, and the test material would be the sodium salt of asulam for all required studies;
d) they submitted the salt data in support of #264-451 MP - acid and #264-447 EP - salt but was informed by RD (J. Miller) that EPA considers asulam and its sodium salt as two distinct actives, and consequently applied for registration of the sodium salt of asulam (Reg # 264-LNL);
e) they submitted information on guideline series 61, 62 and stability on 9/21/92 in response to the EPA review dated 2/8/91 and believe all remaining product chemistry data deficiencies should now be fulfilled.

With this additional information from the registrant, CBRS will evaluate the adequacy of all available product chemistry data for reregistration of asulam (acid, EPA Reg # 264-451). For product chemistry data requirements for the sodium salt of asulam (EPA Reg # 264-LNL), refer to CBRS review # 10654 (DP Barcode: D183102, L. Cheng, 2/9/93).

61-1 Product Composition

According to the Asulam Reregistration Standard Update, 1/15/91, the Guidance Document (12/87) required all new product-specific data concerning product composition of asulam. Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. The following information must be provided for the reregistration of asulam: the chemical name and nominal concentration of each impurity that is $\geq$ 0.1% in the manufactured asulam. (At least some of the impurities and some of the impurity levels present in asulam are expected to be different from those present in the sodium salt of asulam.)

61-2 Starting Materials and Manufacturing Process

According to the Asulam Reregistration Standard Update, 1/15/91, the Guidance Document (12/87) required all new generic and product-specific data concerning the manufacturing process of asulam and a description of the beginning materials used in the process. Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. For reregistration of asulam, the manufacturing process of asulam and the starting materials used for its manufacture must be described (even though the differences between the manufacture of asulam and its sodium salt may be very minor).

61-3 Discussion of the Formation of Impurities

According to the Asulam Reregistration Standard Update, 1/15/91, the Guidance Document (12/87) required all new generic and product-specific data concerning the formation of impurities during and after the manufacturing process, and possible contamination from packaging materials. Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. For reregistration of asulam, relevant data for asulam must be submitted. (Impurities present in asulam and those present in the sodium salt of asulam are not expected to be identical.)

62-1 Preliminary Analysis

The Registration Standard Science chapter (8/28/87) required preliminary analysis be conducted on 5 or more representative samples of asulam. The registrant in response submitted preliminary analysis results for the sodium salt of asulam which were discussed in the Reregistration Standard Update (1/15/91). For reregistration of asulam, data for asulam must be submitted. (Asulam and its sodium salt are distinct compounds.)

62-2 Certificate of Ingredient Limits

Data submitted in response to the Registration Standard Guidance Document were for the sodium salt of asulam (discussed in the Reregistration Standard Update, 1/15/91). Limits for asulam must be submitted for its reregistration (since the ingredients in asulam are different.)

62-3 Analytical Methods to Verify Certified Limits

Methods submitted in response to the Registration Standard Guidance Document were for the sodium salt of asulam (discussed in the Reregistration Standard Update, 1/15/91). CBRS withholds its judgement as to the adequacy of these methods until data under 61-3, 62-1 and 62-2 for asulam have been submitted.

63 Physical and Chemical Characteristics

Data for asulam (technical material) are available in the Reregistration Standard Update, 1/15/91, for the following: color (63-2), physical state (63-3), boiling point (63-6, not applicable), density (63-7), solubility (63-8), vapor pressure (63-9), octanol/water partition coefficient (63-11), and pH (63-12).

Data for odor (63-4; a more qualitative description), melting point (63-5; decomposition temperature should be indicated if compound decomposes), dissociation constant (63-10; the method and substance used), and stability (63-13; in the presence of sunlight, metals, and metal ions) with the technical material as the test substance are outstanding.

Product-specific data for asulam to satisfy storage stability (63-17) and corrosion characteristics (63-20) are outstanding.

CONCLUSIONS AND RECOMMENDATION

61-1 Product Composition

Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. The following information must be provided for the reregistration of asulam: the chemical name and nominal concentration of each impurity that is $\geq$ 0.1% in the manufactured asulam.

61-2 Starting Materials and Manufacturing Process

Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. For reregistration of asulam, the manufacturing process of asulam and the starting materials used for its manufacture must be described.

61-3 Discussion of the Formation of Impurities

Data submitted by the registrant in response to the Guidance Document and reviewed in the Reregistration Standard Update relate to the sodium salt of asulam. For reregistration of asulam, all new generic and product-specific data concerning the formation of impurities during and after the manufacturing process, and possible contamination from packaging materials data for asulam must be submitted.

62-1 Preliminary Analysis

The registrant submitted preliminary analysis results for the sodium salt of asulam which were discussed in the Reregistration

Standard Update (1/15/91). For reregistration of asulam, preliminary analysis conducted on 5 or more representative samples of asulam must be submitted.

62-2 Certificate of Ingredient Limits

Data submitted in response to the Registration Standard Guidance Document were for the sodium salt of asulam (discussed in the Reregistration Standard Update, 1/15/91). Limits for asulam must be submitted for its reregistration.

62-3 Analytical Methods to Verify Certified Limits

Methods submitted in response to the Registration Standard Guidance Document were for the sodium salt of asulam (discussed in the Reregistration Standard Update, 1/15/91). CBRS withholds its judgement as to the adequacy of these methods until data under 61-3, 62-1 and 62-2 for asulam have been submitted.

63 Physical and Chemical Characteristics

Data for asulam (technical material) are available for the following: color (63-2), physical state (63-3), boiling point (63-6, not applicable), density (63-7), solubility (63-8), vapor pressure (63-9), octanol/water partition coefficient (63-11), and pH (63-12).

Data for odor (63-4; a more qualitative description), melting point (63-5; decomposition temperature should be indicated if compound decomposes), dissociation constant (63-10; the method and substance used), and stability (63-13; in the presence of sunlight, metals, and metal ions) are outstanding.

Product-specific data for asulam to satisfy 63-17 and 63-20 are outstanding.

The registrant needs to submit additional data and information specified under product chemistry guideline series 61, 62, and 63 in order to reregister asulam. For product chemistry data requirements for the sodium salt of asulam, refer to CBRS review # 10654 (DP Barcode: 183102, L. Cheng, 2/9/93).

Note to PM: If the registrant does not intend to market any products that contain asulam (acid) as the active ingredient, it may be advantageous for them to withdraw the registration of asulam (EPA Reg # 264-451).

cc:Circ, RF, Reg Std File, Cheng
RDI:FSuhre:2/1/93:MMetzger:2/8/93:EZager:2/8/93
H7509C:CBRS:LCheng:CM#2:RM810D:1/29/93:03:ASULAM\PRDTCHEM

PRODUCT CHEMISTRY

Case No.: 0265 Case Name Asulam (acid)
Chemical No(s).: 106901
Chemical Name(s): Methyl sulfanilylcarbamate
Registrant: Rhone-Poulenc

| Guideline Number | Is requirement applicable? | Does summary or available information indicate MRID is a candidate for Phase 5 review? | Are additional data required?[1] | MRID Number |
|---|---|---|---|---|
| 61-1 | Y | N | Y | |
| 61-2 | Y | Y | Y | |
| 61-3 | Y | N | Y | |
| 62-1 | Y | Y | Y | |
| 62-2 | Y | N | Y | |
| 62-3 | Y | N | I | |
| 63-2 | Y | Y | N | |
| 63-3 | Y | Y | N | |
| 63-4 | Y | P | Y | |
| 63-5 | Y | P | Y | |
| 63-6 | N | N/A | N | |
| 63-7 | Y | Y | N | |
| 63-8 | Y | Y | N | |
| 63-9 | Y | Y | N | |
| 63-10 | Y | P | Y | |
| 63-11 | Y | Y | N | |
| 63-12 | Y | Y | N | |
| 63-13 | Y | N | Y | |
| 63-14 | N | N/A | N | |
| 63-15 | N | N/A | N | |
| 63-16 | N | N/A | N | |
| 63-17 | Y | N | Y | |
| 63-18 | N | N/A | N | |
| 63-19 | N | N/A | N | |
| 63-20 | Y | N | Y | |

Key: Y-yes; N-no; I-a decision cannot be made at this time; S-fully satisfies requirement; P-partially; N/A-not applicable; U-unsatisfactory.

0265.PC2 (.Cheng, CBRS review # 10955, 2/9/93

[1] Based on the data provided in the Reregistration Standard Update, 1/15/91.